THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte DANFORTH BIOMEDICAL INC.

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Appeal No. 97-3126
Reexamination Control No. 90/003,907[1]

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ON BRIEF

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Before CALVERT, MEISTER, and STAAB, Administrative Patent Judges.

MEISTER, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims 1, 4-6, 8-12 and 14-26, the only claims remaining in the application. We affirm-in-part.

The appellant's invention pertains to a catheter of the type having a balloon and a seal that is formed by close-tolerance surfaces and serves to prevent leakage of inflation media from

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[1] Request filed July 31, 1995, for the Reexamination of U.S. Patent No. 5,209,728, issued May 11, 1993, based on Application 07/946,828, filed September 16, 1992; which according to the appellant is a continuation of Application 07/430,702, filed November 2, 1989, now abandoned.

the catheter. Independent claim 1 is further illustrative of the appealed subject matter and reads as follows:

1. A catheter having a balloon at a distal end thereof, the balloon having an interior that is inflatable upon pressurization with inflation media and a seal preventing leakage of inflation media from the catheter, the seal comprising:

a first region disposed on a first portion of the catheter and having a first surface contour; and

a second region disposed on a second portion of the catheter, the second region being movable with respect to the first region and having a second surface contour corresponding to the first surface contour, the first and second regions spaced apart by a distance sufficiently small to prevent inflation media from flowing therebetween, thereby forming a seal, the seal positioned to commence substantially at the distal end of the balloon and extend distally therefrom and to separate a first volume within the catheter that is in communication with the balloon interior from a second volume that is in communication with the exterior of said catheter.

The references relied on by the examiner are:

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|---|---|---|---|
| Machold et. al. | (Machold) | 4,976,720 | Dec. 11, 1990 (filed Jul. 18, 1988) |
| Burns | | 5,032,113 | Jul. 16, 1991 (filed Apr. 13, 1989) |
| Engelson et al. | (Engelson) | 5,135,494 | Aug. 4, 1992 (parent filed Aug. 1, 1988) |

Claims 1, 4-6, 10, 12, 14, 15, 17, 20 and 21 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Engelson.[2]

Claims 8, 9, 11, 16, 18 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over Engelson in view of Machold.

Claims 22-26 stand rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Burns.

The examiner's rejections are explained on pages 3-5 of the answer. Rather than reiterate the arguments of the appellant and examiner in support of their respective positions, reference is made to pages 10-15 of the brief and pages 6 and 7 of the answer for the details thereof.

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[2] In view of the recent decision by our reviewing court in ***In re Portola Packaging Inc.***, 110 F.3d 786, 791-92, 42 USPQ2d 1295, 1300 (Fed. Cir. 1997), we note that the parent application of Engelson matured into Patent No. 4,813,934 and was cited during the prosecution of the appellant's patent which is the subject of the instant reexamination proceeding. This patent, (Engelson '934) however, contains subject matter that is only in part common with Engelson and, more specifically, does not contain the specific structure relied on by the examiner for a teaching of a seal achieved by close tolerances.

**OPINION**

As a preliminary matter, we observe that the appellant has stated on page 9 of the brief that the claims on appeal stand or fall together in the following manner: (1) claims 1, 4-6, 8-12 and 14-16 as a first group, (2) claims 17-21 as a second group and (3) claims 22-26 as a third group. Accordingly, (1) claims 4-6, 8-12 and 14-16 will stand or fall with independent claim 1, (2) claims 18-21 will stand or fall with independent claim 17 and (3) claims 23-26 will stand or fall with independent claim 22. See 37 CFR § 1.192(c)(7).

We have carefully reviewed the appellant's invention as described in the specification, the appealed claims, the prior art applied by the examiner and the respective positions advanced by the appellant in the brief and reply brief and by the examiner in the answer. As a consequence of this review, we will sustain the rejections of claims 1, 4-6, 8-12 and 14-21 and reverse the rejections of claims 22-26. Our reasons for these determinations follow.

Considering first the rejection of claims 1, 4-6, 10 12, 14, 15, 17, 20 and 21 under 35 U.S.C. § 102(e) as anticipated by Engelson, it is the appellant’s position that:

> Engelson *et al*. neither disclose nor suggest a seal of the type recited in Appellants' claims. As the Examiner has recognized, Engelson *et al*. disclose a guidewire and balloon-tipped catheter combination where the balloon has an aperture at its distal end, and where there is "limited clearance" between the guidewire and the aperture. The purpose and function of the "limited clearance," according to the patent itself, is to allow the passage of fluid from the balloon interior out through the aperture, and to do this at a controlled rate. The limited clearance thus serves as a flow restriction valve, and the patent itself recognizes this by characterizing the limited clearance as a "valve structure" . . . . Thus, the guidewire and catheter body are designed to allow fluid to pass from the catheter interior to the target site in the patient's vasculature at a slow, controlled rate. Supplying fluid to the target site is thus both the purpose and the result in the Engelson *et al*. structure. Appellants' invention is quite the opposite: placing the two surfaces, one having a "contour corresponding" to the other, close enough together "to prevent inflation media from flowing therebetween," as recited in claim 1 of this appeal.
>
> Even if the "limited clearance" of the Engelson *et al*. valve were extremely small, the valve could not operate as a seal. This is because the distal end of the guidewire is a coil whose surface does not "correspond" to the opposing surface of the aperture and is thus not capable of forming a seal. [Brief, page 10.]

We are unpersuaded by the appellant's arguments. The terminology in the claims of a reexamination application is to be

given its broadest reasonable interpretation consistent with the specification and limitations from the specification are not to be read into the claims. ***In re Yamamoto***, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984). Moreover, anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or the recognition of inherent properties that may be possessed by the prior art reference. ***See Verdegaal Brothers Inc. v. Union Oil Co. of California***, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987). A prior art reference anticipates the subject matter of a claim when a reference discloses, either expressly or under the principles of inherency, each and every element of a claimed invention. ***See RCA Corp. v. Applied Digital Data Systems, Inc.***, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). The law of anticipation, however, does not require that the reference teach what the appellant is claiming, but only that the claims on appeal "read on" something disclosed in the reference. ***See Kalman v. Kimberly-Clark Corp.***, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983).

Here, we initially observe that the “purpose” of Engelson’s limited clearance between guide wire 40 and aperture 30 is not to

deliver fluid to a target site in the patient's vasculature at a slow, controlled rate as the appellant would have us believe. Instead, Engelson expressly states that:

> The limited clearance between the guide wire is selected so as to allow the balloon to be inflated to a greater (smaller clearance) or lesser (larger clearance) balloon pressure, and/or to allow a desired leakage rate from the balloon in the inflated state. [Column 6, lines 9-14.]

It is thus readily apparent that purpose of the limited clearance is to allow the balloon to be inflated to a selected pressure and/or allow a desired leakage rate. Although Engelson in column 9, lines 12-13, states that a "therapeutic, vasoocclusive, and/or radio-opaque material" may be delivered to a target site, in this mode of operation the guide wire 40 is **completely removed** from the aperture 30 (see column 9, lines 10-12).

It is true that Engelson's limited clearance is selected so as to allow the balloon to be inflated to a desired pressure "and/or to allow a desired leakage rate from the balloon in the inflated state" while independent claims 1 and 17 each expressly require that the first and second regions be "spaced apart by a distance sufficiently small to prevent inflation media from

> In general, the competence of the seal is directly related to the common surface area and fluid viscosity and inversely related to the degree of separation, and the pressure differential.
>
> Although depending upon manufacturing tolerances leakage may be inevitable with a seal of this design, a seal can be constructed in this manner that provides sufficient fluid retention to meet the functional requirements of interventional catheters. In general, interventional catheters are prepared with contrast media, a particularly viscous fluid that is relatively easily contained by a seal of this nature. [Column 11, lines 40-52.]

Thus, it appears from the appellant's specification that the seal is designed to provide "sufficient" fluid retention to meet the functional requirements of the catheter much in the same manner as Engelson's arrangement (note column 6, lines 32-38). It is further apparent that the claimed "sufficiently small" distance is at least in part dependent upon the viscosity of the fluid used in the catheter and, even though a particularly viscous fluid is used, some leakage may be inevitable. Accordingly, consistent with the appellant's specification, one of ordinary skill in this art would interpret the recitation set forth in independent claims 1 and 17 of "a distance sufficiently small to prevent inflation media from flowing therebetween" to include a distance which allows at least some leakage.

Moreover Engelson, as the examiner has noted, shows:

> a tube (e.g. 14 in figures 1-1 or 52 in figure 4 or 74, 80 in figure 5) having a lumen, and a guidewire (36 in figures 1-3 or 66 in figure 4 or 78 in figure 5) wherein the difference between the diameter of the lumen (at the inner diameter of ring 28 in figures 1-3 or ring 62 in figure 4 or ring 80 in figure 5) and the diameter of the guide wire is **0.0005 inch** (note the reference to 0.5 mils in col. 6, lines 1-3). This gap is so small that an essentially fluid-tight seal is inherently formed. In support of this assertion the Kraus et al. Patent No. 5,209,728 [which is the subject matter of this reexamination application] indicates that a fluid-tight seal is formed when a guidewire is separated from the inner wall of a tube by as much as **0.001 inch** (col. 13, lines 14-23) which is an even greater separation distance than that disclosed by Engelson et al. [Answer, page 2.]

Particularly in view of the fact that Engelson discloses a spacing between the first and second regions which is well within the range of 0.001 to 0.0001 inches disclosed by the appellant in column 13, lines 17 and 18, we are of the opinion that the examiner has a reasonable basis for concluding that Engelson can be considered to inherently disclose a “seal” as broadly set forth in independent claims 1 and 17. Where, as here, there is a sound basis to believe that the critical function for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art

device, it is incumbent upon an appellant to prove that the prior art device does not in fact possess the characteristics relied on. ***See In re Spada***, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); ***In re Glass***, 474 F.2d 1015, 1019, 176 USPQ 529, 532 (CCPA 1973) and ***In re Ludtke***, 441 F.2d 660, 664, 169 USPQ 563, 566-67 (CCPA 1971). While the appellant has asserted that the limited clearance of Engelson "could not" operate as a seal, counsel's arguments in the brief cannot take the place of evidence. ***See In re De Blauwe***, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984), ***In re Payne***, 606 F.2d 303, 315, 203 USPQ 245, 256 (CCPA 1979) and ***In re Pearson***, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974).

With respect to independent claim 1, Engelson in Fig. 5 shows the seal commencing at the distal end and, with respect to independent claim 17, in Figs. 2 and 3 shows the seal commencing at a location "within the confines" of the balloon.

As to the appellant's contention that Engelson does not disclose a second surface contour "corresponding" to a first surface contour, we note that The American Heritage Dictionary[3] defines "correspond" as -- 2. To be similar, parallel,

[3] The American Heritage Dictionary, Second College Edition, 1982, Houghton Mifflin Company, Boston, MA.

equivalent, or equal in character, quantity, origin, structure, or function . . . --. This being the case, we are of the opinion that the second region 40 of Engelson can be considered to have a contour "corresponding" to the contour of the first region 30.

Since we find response in Engelson, either expressly or under the principles of inherency, for each and every feature set forth in independent claims 1 and 17, we will sustain the rejection of claims 1, 4-6, 10 12, 14, 15, 17, 20 and 21 under 35 U.S.C. § 102(e) based on this reference.

We now turn to the rejections under 35 U.S.C. § 103 of (1) claims 1, 4-6, 10 12, 14, 15, 17, 20 and 21 as being obvious over Engelson and (2) claims 8, 9, 11, 16, 18 and 19 as being unpatentable over Engelson in view of Machold. As to the rejection of claims 1, 4-6, 10 12, 14, 15, 17, 20 and 21 based on Engelson alone, we initially note that lack of novelty is the ultimate or epitome of obviousness. ***In re Fracalossi***, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982). We also note that the issue of obviousness is not only determined by what the references expressly state but also is determined by what they would fairly suggest to those of ordinary skill in the art. ***See, e.g., In re Delisle***, 406 F.2d 1386, 1389, 160 USPQ 806, 808-09 (CCPA 1969) and ***In re Bozek***, 416 F.2d 1385, 1390, 163 USPQ 545,

549-50 (CCPA 1969). Moreover, in evaluating such references it is proper to take into account not only the specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. ***See In re Preda***, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). As we have noted above, Engelson in lines 9-14 of column 6 states that the limited clearance between the guide wire 40 and the aperture 30 is selected so as to allow the balloon to be inflated and at a greater or lesser pressure "and/**or** to allow a desired leakage rate from the balloon in the inflated state" (emphasis ours). In our view, this statement by Engelson would have fairly suggested to the artisan that leakage may be omitted if such were not desired. Thus, even if the arrangement of Engelson wherein a certain amount of leakage was desired is not considered to be a seal, the elimination or prevention of such leakage would have nevertheless been obvious to one of ordinary skill in this art in view of this suggestion by Engelson.

As to the rejection of claims 8, 9, 11, 16, 18 and 19 as being obvious over Engelson in view of Machold, the appellant has

not argued that it would have been unobvious to combine the teachings of these two references in the manner proposed by the examiner.

For the reasons stated above, we will sustain the examiner's rejections under 35 U.S.C. § 103 of (1) claims 1, 4-6, 10 12, 14, 15, 17, 20 and 21 based on Engelson alone and (2) claims 8, 9, 11, 16, 18 and 19 based on the combined teachings of Engelson and Machold.

Considering last the rejection of claims 22-26 under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Burns, the examiner has taken the position that Burns teaches a seal which commences at insert 16; however, we find nothing in Burns which either teaches or fairly suggests a seal as set forth in independent claim 22. The insert 16 of Burns acts as a platform to support the connection of the main shaft 12 and distal outer tube 14 (see column 5, lines 12-16). This insert is further provided with apertures or fluid paths 36 (see Fig. 3) and thus cannot be fairly construed to be a seal as set forth in independent claim 22.

The other embodiments of Burns have similar apertures or are provided with other structure which allows fluid to flow therethrough. Even in the embodiment of Fig. 9 the insert 90 is disclosed as a "ring of porous or permeable material" (see column 7, lines 34 and 35) and thus cannot be considered to be a seal as claimed. Since we find nothing in Burns which either teaches or fairly suggests a seal as set forth in independent claim 22, we will not sustain the rejection of claims 22-26 under 35 U.S.C. § 102(e) or, in the alternative under 35 U.S.C. § 103, based on this reference.

In summary:

The rejections of (1) claims 1, 4-6, 10 12, 14, 15, 17, 20 and 21 under 35 U.S.C. § 102(e) or, alternatively under 35 U.S.C.

§ 103, based on the reference to Engelson alone and (2) claims 8, 9, 11, 16, 18 and 19 under 35 U.S.C. § 103 based on the combined teachings of Engelson and Machold are affirmed.

The rejections of claims 22-26 under 35 U.S.C. § 102(e) or, in the alternative under 35 U.S.C. § 103, based on Burns are reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

**AFFIRMED-IN-PART**

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|---|---|
| IAN A. CALVERT<br>Administrative Patent Judge | ) |
| JAMES M. MEISTER<br>Administrative Patent Judge | ) BOARD OF PATENT APPEALS AND INTERFERENCES |
| LAWRENCE J. STAAB<br>Administrative Patent Judge | ) |

Appeal No. 97-3126
Reexamination Control No. 90/003,907

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APPEAL NO. 97-3126 - JUDGE MEISTER
REEXAMINATION NO. 90/003,907

APJ MEISTER

APJ STAAB

APJ CALVERT

DECISION: **AFFIRMED-IN-PART**

Typed By: Jenine Gillis

**DRAFT TYPED:** 16 Jul 97
Revised: 17 Jul 97

**FINAL TYPED:**